

March 6th, 2019

Alex M. Azar II
Secretary
U.S. Department of Health and Human Services

Scott Gottlieb
Commissioner
Food and Drug Administration

John Michael Mulvaney
Director
Office of Management and Budget

Sent via electronic mail

Re: FDA proposed rule banning electrical stimulation devices

Dear Secretary Azar, Commissioner Gottlieb and Director Mulvaney,

We the undersigned write to express our deep appreciation to see that the final rule for the proposed ban of electrical stimulation devices (ESDs) used to treat self-injurious or aggressive behavior has been placed on the Federal Drug Administration (FDA)'s Fall regulatory agenda. For nearly three years since the FDA initially released its Proposed Rule to ban these devices, and for almost five years since a panel of experts recommended that they be banned, children and adults with disabilities have continued to suffer from painful and dangerous electric shocks. We are relieved that the FDA finally plans to formally recognize what people with disabilities, disability advocates, researchers, psychiatrists and psychologists, families, and the United Nations have long known: these are devices of torture and abuse, and their use must end. We are pleased to see that the agency intends to take action in the coming year to end this abuse.

We further wish to reiterate what we expect from the final rule: a complete, immediate ban of the use of ESDs for behavior modification. In recognition of the severe harm these devices inflict, and in light of the abundant evidence the FDA has reviewed, we do not believe any sort of "phase-down" period or any form of "grandfathering" is warranted. Given the extensive time the FDA has taken to develop the final rule, as detailed below, we urge that it be released in its final form by the 5th anniversary of the panel--April 24th, 2019. Following the issuance of the rule, we expect the FDA to take prompt action to enforce the ban and ensure the safety and well-being of individuals known to have been subject to ESDs. **Secretary Azar and Commissioner Gottlieb, we ask that you devote any and all resources necessary to swiftly review comments and finalize the rule with an immediate effective date and no further delays.** Additionally, we call on the White House to take all steps necessary to ensure that the rule is expeditiously finalized and released.

As you know, concerned citizens and advocacy organizations first wrote to the FDA in March 2010 and again in January 2013, urging that the FDA ban these dangerous and unnecessary devices. In addition, in December 2012, the Centers for Medicare and Medicaid Services issued a letter making clear that use of the graduated electronic decelerator device, and other Level III aversive techniques, is prohibited for individuals receiving Medicaid-funded home and community-based services. Advocates met with FDA representatives in April 2013. A year later, on April 24, 2014, the FDA held a day-long hearing and convened an advisory panel to seek scientific and clinical expert opinion on the risks and benefits associated with other treatment options, the risks and benefits of ESDs for aversive conditioning, and on whether these devices present a substantial and unreasonable risk of illness or injury. The FDA additionally solicited public comment, and deliberated for a full two years before announcing on April 22, 2016 that it had determined that these devices present an

unreasonable and substantial risk of illness or injury that cannot be corrected or eliminated by labeling. Despite having had multiple public comment periods related to the device, FDA allowed an extension of the comment period on the proposed rule from a deadline of May 25 to July 25, 2016. **It has now been over thirty months since that comment period ended.**

The FDA is mandated to protect the health and safety of these individuals and must not delay further.

We appreciate the swift action the FDA has taken under Commissioner Gottlieb's leadership on many products which threaten the health and well being of Americans, particularly young people. Just this past month, the FDA warned against the potential dangers of [teething necklaces and jewelry products](#) sometimes used by autistic people for sensory regulation. **We urge you to treat this matter with the same urgency.** In the nine years since this issue was raised to the FDA, some of our nation's most vulnerable people have been subjected to unbearably painful electric shock for such harmless behaviors as getting out of one's seat, interrupting, whispering, slouching, swearing, or failing to maintain a neat appearance. As the proposed rule recognizes, disabled children and adults are experiencing dramatic short and long term effects from this abusive treatment every day. They cannot afford to wait any longer. **We the undersigned urge HHS and the White House to prioritize and take all actions necessary to ensure this critical rule is immediately finalized and implemented.**

If you have any questions about this letter, please contact Julia Bascom of the Autistic Self Advocacy Network at jbascom@autisticadvocacy.org, or 205-558-4894.

Sincerely,

A Better Life, LLC

ACHIEVA

ACCSES

Access Living

ADAPT

ADAPT DC Metro

ADAPT Chicago

ADAPT Georgia

ADAPT Kansas

ADAPT NY

ADAPT Montana

ADAPT Utah

The Advocacy Institute

Advocates

Alliance

The Alliance for the Betterment of Citizens with Disabilities

Alliance for Citizen Directed Supports

Alliance for Person Centered Accessible Technologies

Allies for Independence

American Academy of Developmental Medicine and Dentistry

AAPD

American Association on Intellectual and Developmental Disabilities

American Association on Health and Disability

American Civil Liberties Union (ACLU)

American Foundation for the Blind

American Network of Community Options and Resources

American Occupational Therapy Association

Autism Science Foundation

The Arc Arapahoe and Douglas

The Arc Michigan
The Arc of Adams County
The Arc of Colorado
The Arc of Hunterdon County
The Arc - Jefferson, Clear Creek & Gilpin Counties
The Arc of Massachusetts
The Arc Mesa County
The Arc Michigan
The Arc of the United States
The Arc of Virginia
The Arc of Weld County
The Arc of West Central Colorado
The Arc of Wisconsin
Architects of Diversity
Association of Developmental Disabilities Providers of Massachusetts
Association of Programs for Rural Independent Living
Association of University Centers on Disabilities
AutCom
Autism Society of America
Autism Society of Los Angeles
Autism Women's Network
Autistic Self Advocacy Network
Bazelon Center for Mental Health Law
Blue Peaks Developmental Services
Boston Center for Independent Living
Brain Injury Association of America
Broadreach Training and Resources, Ltd.
Camphill Soltane
Caldwell Family Services Inc.
California Down Syndrome Advocacy Coalition
Cal-TASH
Center for Behavioral Education and Research, University of Connecticut
Center for Disability Rights
Center for Public Representation
Center on Human Policy, Syracuse University
Central Wisconsin ADAPT
Cerebral Palsy of North Jersey
Chattanooga Autism Center
Children's Freedom Initiative
Collaboration to Promote Self-Determination
Colorado Bluesky Enterprises, Inc.
Colorado Cross-Disability Coalition
Colorado Developmental Disabilities Council
Community Connections, Inc.
Community Link
Community Options, Inc.
Community Outreach
Community Systems, Inc.
The Coordinating Center
The Council of Parent Attorneys and Advocates, Inc.
The Council on Quality and Leadership
Delaware Developmental Disabilities Council

Dept. of Counseling and Special Education, Virginia Commonwealth Univ.

Different Dream Living

Disability Health Access

Disability Inclusion Guild

Disability Law Center- MA

Disability Law Center of Virginia

Disability Law Center of Alaska

Disability Policy Consortium

Disability Power & Pride

Disability Rights Center

Disability Rights Center of Kansas

Disability Rights Center-NH

Disability Rights California

Disability Rights Connecticut

Disability Rights DC at University Legal Services

Disability Rights Education & Defense Fund

Disability Rights Florida

Disability Rights Maine

Disability Rights Maryland

Disability Rights Mississippi

Disability Rights North Carolina

Disability Rights North Dakota

Disability Rights New Jersey

Disability Rights New York

Disability Rights Oregon

Disability Rights Pennsylvania

Disability Rights Wisconsin

Diverse City Press, Inc.

Down Syndrome Alliance of the Midlands

Down Syndrome Association of Central Florida

Down Syndrome Association of Delaware

Down Syndrome Association of Middle Tennessee

Down Syndrome Association of West Michigan

Down Syndrome Awareness Group of East Tennessee

Down Syndrome Connection of the Bay Area

Easterseals

Education Advocacy Coalition

Endless Possibilities In The Community

Epilepsy Foundation

Equip for Equality

Exceptional Parent Magazine

Families of Children on the Autism Spectrum (FOCAS)

Family Residences and Essential Enterprises, Inc.

Family Voices

Frontier Community Services

Gail Jacob and Associates

Georgia Advocacy Office

Georgia Council on Developmental Disabilities

Governor's Advisory Council for Exceptional Citizens (GACEC)

HIGH IMPACT Mission-based Consulting & Training

Hills & Dales Child Development Center

Hope House Foundation

Human Services Research Institute
I CAN Missouri Foundation
Imagine
Inclusion Innovations
Independent Environments, Inc.
Institute for Community Inclusion, University of Massachusetts Boston
Institute on Disabilities, Temple University
Integrated Quality Management Approach (IQMA) Team
InVision Human Services
Jannirose JOY LLC
Japanese Speaking Parents Association of Children with Challenges
Job Path, Inc.
Kentucky Association of Private Providers (KAPP)
Kentucky Protection and Advocacy Division
Keystone Human Services
Kern Down Syndrome Network
Koinonia Homes, Inc.
L'Arche Syracuse
Lakeshore Foundation
The Learning Community for Person Centered Practices, Inc.
Liberty Resources Inc.
LifeShare
Linda H. Rammler, Consultants
Living Well Disability Service
Lutheran Services in America Disability Network
Marbridge Foundation
Maryland Association of Community Services
Maryland Coalition of Families
Maryland Coalition for Inclusive Education
Mental Health America
Mental Health Legal Advisors Committee, Supreme Judicial Court of Massachusetts
Metro Boston Recovery Learning Community
Michigan Protection and Advocacy Service
Mosaic
M-POWER
National Leadership Consortium on Development Disabilities
National Alliance for Direct Support Professionals
National Alliance on Mental Illness
National Alliance for Mental Illness - Greater Boston Consumer Advocacy Network
NAACP
National Association of Councils on Developmental Disabilities
National Association of Nurses with Disabilities (NOND)
National Association of State Directors for Developmental Disabilities Services
National Association of State Directors of Special Education (NADSE)
National Association of the Deaf (NAD)
National Association of State Head Injury Administrators
National Coalition for Mental Health Recovery
National Consumer Voice for Quality Long-Term Care
National Council on Independent Living
National Disability Rights Network
National Down Syndrome Congress
National Down Syndrome Society

National Empowerment Center
National LGBTQ Task Force
National Rehabilitation Association
Native American Disability Law Center
Neighbours, Inc
NorthStar Supported Living Services, Inc.
Not Dead Yet
Occupy the Judge Rotenberg Center
Oklahoma Community-based Providers, Inc.
Ollibeau
Options in Community Living, Inc.
Orange Grove Center
Oregon Resource Association (ORA)
Oregon Supported Living Program
Parent 2 Parent USA
Parents of Adults with Disabilities in Colorado
Pastoral Ministry with Persons with Disabilities
Play to Learn...Learn to Play, Inc.
Protection and Advocacy for People with Disabilities - SC
Quality Trust for Individuals with Disabilities
Queerability
Research and Training Center on Community Living, University of Minnesota
The Resource Exchange, Inc.
Respect ABILITY Law Center
RISE Services, Inc.
Riverside Training Centers, Inc.
Rocky Mountain Down Syndrome Association
Second Thoughts MA: Disability Rights Advocates against Assisted Suicide
SEEC
Shared Support Maryland, Inc.
Southeastern Developmental Services
Southern Arizona Network for Down Syndrome
Spaulding Support Services
Starpoint
Statewide Independent Living Council of Alaska
Sunshine Social Club
Support, Inc.
Syntiro
TASH
TASH New England
Teaching Learners with Multiple Needs/Ahern TEC
The THRIVE Network
Topeka Independent Living Resource Center
Transition Consults, LLC
UMKC Institute for Human Development
Unbound Books Autism Acceptance Library
United Cerebral Palsy
United Spinal Association
Uplift, Inc.
Values Into Action, NJ
Values Into Action, PA
Velocardiofacial Syndrome Texas, Inc.

Vision for Equality
Vita Community Living Services
Washington Metro Disabled Students Collective
Western Massachusetts Recovery Learning Community
Wings to Fly Therapy and Play Center
Wisconsin Board for People with Developmental Disabilities
Wisconsin Upside Down

Cc: Jeffrey Shuren
Director
Center for Devices and Radiological Health

Roger Severino
Director
Office of Civil Rights

Lance Robertson
Administrator
Administration on Community Living

Neomi Rao
Administrator
Office of Information and Regulatory Affairs

